DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 11, 2015

Sanovas, Inc.
c/o Cynthia Nolte, Ph.D., RAC
Senior Director of Regulatory Affairs
ICON Clinical Research LLC
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K150280
Trade/Device Name: PulmoVia Working Channel
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid)
Regulatory Class: Class II
Product Code: EOQ
Dated: April 22, 2015
Received: April 22, 2015

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150280

Device Name
PulmoVia Working Channel

Indications for Use *(Describe)*
The PulmoVia Working Channel is intended to be used as an access channel through which a bronchoscope and other endoscopic tools may be introduced to treat targeted tissue of the airways. The PulmoVia Working Channel can also provide means for bronchoalveolar lavage. The PulmoVia Working Channel is indicated for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

Sanovas, Inc.
PulmoVia Working Channel

(per 21CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

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Phone: 415-729-9391
Contact: Roy Morgan, VP of Research and Development
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Date Prepared: June 10, 2015

2. DEVICE NAME

Trade Name:	PulmoVia Working Channel
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Classification Panel:	Ear, Nose, and Throat Devices Panel
Classification Regulation:	21 CFR 874.4680
Device Classification:	Class II
Product Code:	EOQ

3. PREDICATE DEVICES

- LungPoint™ Tools (LungPoint Sheath and LungPoint Dilation Balloon), K131234
- KimVent BAL Cath Bronchial Aspirate Sampling Catheter, K112562
- Olympus Guide Sheath, K060243

4. DEVICE DESCRIPTION

The PulmoVia Working Channel is a single-use disposable, terminally-sterilized device for transtracheal access to bronchi of the lungs, and consists of a hollow tube with an angled flexible tip to assist in anatomical navigation. A radiopaque marker is located 4 mm from the distal tip to aid in localization under fluoroscopy/CT. Printed markings are positioned at 370 mm from the distal tip, and every 50 mm proximally from that point. The distal tip of the device has a pliable leading edge.

The device also contains a disposable Tuohy-Borst adaptor to allow use of third-party devices such as ultrathin bronchoscopes. The full assembly will be packaged in a polyethylene and Tyvek pouch, sterilized via ethylene oxide (EO).

5. INDICATION FOR USE/INTENDED USE

The PulmoVia Working Channel is intended to be used as an access channel through which a bronchoscope and other endoscopic tools may be introduced to treat targeted tissue of the airways. The PulmoVia Working Channel can also provide means for bronchoalveolar lavage. The PulmoVia Working Channel is indicated for adult patients.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Both the proposed PulmoVia Working Channel and the predicate Lung Point Sheath are catheters designed for use with a bronchoscope to reach a targeted area of the bronchial tree. The working length of the PulmoVia Working Channel (485 mm) is less than that of the predicate Lung Point Sheath and reference devices. The inner diameter of the catheter (5.25 mm) is greater than that of the Lung Point and Olympus Guide Sheath. The inner diameter was established in order to be compatible with bronchoscopes with an OD of 4.0 mm.

The predicate Lung Point Sheath is supplied with a stylet. Neither the proposed PulmoVia Working Channel nor the reference device Olympus Guide Sheath are supplied with a stylet.

The proposed PulmoVia Working Channel has an angled, flexible tip to aid in navigation of the PulmoVia Working Channel within the lung. The BAL Cath tip is also designed with a flexible tip.

The materials used for the proposed device are provided in the side-by-side comparison table. Like the predicate devices, the PulmoVia Working Channel sheath and connector are composed of polymers. As will be discussed in Section 7, the PulmoVia Working Channel meets the biocompatibility requirements of ISO 10993-1:2009 for the nature and duration of contact.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Non-clinical performance testing consisted of sterility, shelf-life, packaging validation, transport, biocompatibility and mechanical bench testing which demonstrated that the device met all mechanical design and safety requirements.

The biocompatibility testing included:

- Cytotoxicity (ISO 10993-5:2009, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity)

- Irritation/ Intracutaneous (ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)
- Sensitization (ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)
- Acute systemic toxicity (ISO 10993-11:2006, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity)
- Pyrogenicity (ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity)

The mechanical testing included: (Side by side testing indicated by an asterisk *)

- Pull test*
- Torque test*
- Kink test*
- Bend test*
- Leak test*
- Vacuum test*
- Operating temperature/humidity test*
- Radiopaque test
- Gravity fed hydrostatic flow test*

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical studies were performed using the PulmoVia Working Channel. Usability assessments were conducted in a simulated use environment to optimize the safety of the device design and validate the usability of the device. The results demonstrated that users can operate the PulmoVia Working Channel safely and effectively.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Non-clinical testing confirms that the PulmoVia Working Channel is sterile, has a packaging system adequate to maintain sterility and transportation hazards, and a validated shelf life. The PulmoVia Working Channel is biocompatible and side by side testing confirms that the proposed device has equivalent physical and mechanical characteristics to the identified predicates. Human factors testing confirms that users can operate the PulmoVia Working Channel safely and effectively.

The similarities in intended use, operational characteristics, functional technological characteristics and conclusions drawn from nonclinical testing between the proposed PulmoVia Working Channel and the predicate LungPoint Sheath and KimVent BAL Cath lead to a conclusion of substantial equivalence between the proposed and predicate devices. A side-by-side comparison of the predicate devices and the proposed device is provided in the table at the end of this section.

Side-by-Side Comparison of the PulmoVia™ Working Channel with the LungPoint™ Tools and Reference Devices

Feature	PulmoVia™ Working Channel (Proposed)	LungPoint™ Tools K131234 (Predicate)	Olympus Guide Sheath K060243 (Reference)	BAL Cath* K112562 (Reference)
Indication for Use	The PulmoVia Working Channel is intended to be used as an access channel through which a bronchoscope and other endoscopic tools may be introduced to treat targeted tissue of the airways. The PulmoVia Working Channel can also provide means for bronchoalveolar lavage. The PulmoVia Working Channel is indicated for adult patients.	The LungPoint Sheath is intended to be used as a working channel through which endoscopic tools may be introduced to targeted tissue. Not for pediatric use.	The instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories or ultrasound probe to the targeted area within the respiratory organs.	The BAL Cath is used in the diagnosis of diffuse lung disease by allowing collection of bronchoalveolar lavage (BAL) specimens from deep within the lung. The use of a bronchoscope is not necessary. This catheter is used in adult intubated patients.
Single Use	Single use	Single use	Single use	Single use
Sterile	Yes (Ethylene oxide)	Yes (E-beam)	Yes	Yes
Catheter Working Length	485 mm	900 mm	1050 mm	Not known
Catheter Internal Diameter (ID)	5.25 mm	2.0 mm	2.1 mm	4 mm
Maximum Catheter Outer Diameter (OD)	6.0 mm	2.65 mm	2.7 mm	5.2 mm
Bronchoscope Compatibility	Max OD: 4.0 mm Min Working Length: 600 mm	Not known	Not known	Not used with a bronchoscope
Catheter Length	495 mm	975 mm	900 mm	Not known
Tuohy-Borst Adaptor	Yes	No	Not known	Not known
Stylet	No	Yes	No	No
Distal Tip	Angled, flexible	Not known	Not pliable	Flexible, directional
Radiopaque	Yes	Yes	Yes	Yes

Feature	PulmoVia™ Working Channel (Proposed)	LungPoint™ Tools K131234 (Predicate)	Olympus Guide Sheath K060243 (Reference)	BAL Cath* K112562 (Reference)
Markers				
Materials	**Extrusion:** Tecothane and Pebax **Marker Band:** Platinum-Iridium **Hub:** Polycarbonate **Tuohy Borst Connector:** Polycarbonate with silicone gasket	**Extrusion:** Not known^ **Marker band:** Not known^	**Extrusion:** Polymer^ **Marker band:** Radio-opaque metal **Accessory Port:** Polymer^ **Tri-Channel Connector**: Polymer^	**Extrusion:** Polymer^ **Marker band:** Not known^ **Collar:** Polymer^

*BAL Cath: Kimberly-Clark KimVent BAL Cath Bronchial Aspirate Sampling Catheter
^Material composition is not known